K110048

510(k) SUMMARY

SpineMatrix CERSR® Electromyography System with Electrode Array

JAN 26 2011

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

SpineMatrix, Inc.

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Contact Person: Tamala Wampler
VP of Quality Assurance and Regulatory Affairs

Date Prepared: 1/5/2011

Name of Device: CERSR® Electromyography System with Electrode Array

Common or Usual Name: Electromyographic System

Classification Name: 21 CFR 890.1375 Diagnostic Electromyograph, Class II

Predicate Devices

Paraspinal Diagnostic Corporation CERSR® Electromyography System

Purpose of the Special 510(k) notice.

The SpineMatrix CERSR® Electromyography System is a modification to the PDC CERSR® Electromyography System

Intended Use

The CERSR® Electromyography System is intended to be used by properly trained technicians and/or physicians in clinical settings. The CERSR® Electromyography System is indicated for use to monitor and display the bioelectric signals produced by muscles to aid in the diagnosis and prognosis of muscular disease or dysfunction.

Technological Characteristics

The CERSR® is an Electromyography System. The CERSR® Electromyography System is substantially equivalent to the legally marketed predicate electromyography system. Like most electromyographic systems, CERSR® allows for the monitoring and displaying of the bioelectrical signals generated by muscles.

The CERSR® Electromyography System is specifically designed for a real-time recording of muscle electrophysiology. The CERSR® Electromyography System allows for a real-time recording from multiple locations by applying an array of surface electrodes over the anatomical region of interest. Each electrode is connected to its own channel with a preamplifier, amplifier, buffers and filters. The CERSR® Electromyography System produces a user display of the myoelectric signals. These recordings may be viewed in one of three standard formats, as a typical waveform, RMS display or a frequency spectral analysis plot.

The SpineMatrix CERSR® Electromyography System has the same fundamental scientific technological characteristics as the PDC CERSR® Electromyography System, to which it is a modification. There have been no changes made to the fundamental scientific technology of the system, which consists of the following components: 1) a system cart comprised of a CPU; 2) a mouse and keyboard; 3) monitor; 4) printer; 5) two buffer amplifiers; 6) power distribution box, which contains a filter buffer box; 7) isolation transformer; 8) two power supplies; and 9) a static ground system. The CERSR® system contains software and includes a disposable electrode array. Additional accessories provided with the system include a goniometer, a flexible transparent ruler, and two 3-pound weights. The SpineMatrix CERSR® System components described above are the same as in the predicate device.

The principle purpose of the modifications that have been made is to upgrade the electronic components of the device and its accessories to contemporary computer equipment, printer, etc. Corresponding modifications to the software have been made to accommodate the changes in hardware. No new features or capabilities have been added to the software. None of the changes were made as a result of adverse events with the previous system. Rather, the changes that were made were implemented for purposes of improved user convenience and/or system robustness.

The following performance testing was completed to demonstrate substantial equivalency of the CERSR® Electromyography System to the legally marketed device:

- IEC 60601-1:1995, Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1-2:2001, Medical Electrical Equipment, Part 1-2: General Requirements for Safety-Collateral Standard: Electromagnetic Compatibility-Requirements and Tests
- IEC 61000-3-2:2006, Electromagnetic compatibility- Part 3-2 Limits –Limits for harmonic current emissions (Equipment Input Current ≤16 Amps Per Phase)
- IEC 61000-3-3:2005, Electromagnetic compatibility- Part 3-3 Limits –Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems for equipment with rated current ≤16 amps per phase and not subject to conditional connection
- ISO 10993-10:2002, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed Type Hypersensitivity
- ISO 10993-10:2009, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed Type Hypersensitivity
- ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for Cytotoxicity, In Vitro Methods
- ISO 10993-1: 2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing
- IEC 60601-1-4:2000 Medical electrical equipment - Part 1-4: General Requirements for safety - Collateral Standard: Programmable electrical medical systems.

- ASTM D4169 – 09, Standard Practice for Performance Testing of Shipping Containers and Systems (Cycle 12 Level III)
- ASTM D7386 – 08. Standard Practice for Performance Testing of Packages for Single Parcel Delivery.

The CERSR® Electromyography System nonclinical performance testing demonstrated that this device performs as safely and effectively as the legally marketed device. No new issues were raised in the electrical safety/electromagnetic compatibility testing, biocompatibility testing, software verification and validation testing, or packaging/shipping testing of the modified device.

Substantial Equivalence

The SpineMatrix CERSR® Electromyography System has the exact same intended use and indications for use as the PDC CERSR® Electromyography System. The minor differences in the hardware and software do not raise any new questions of safety or effectiveness. Thus, the CERSR® Electromyography System is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Spinematrix, Inc.
c/o Hogan Lovells US LLP
Ms. Janice M. Hogan
1835 Market Street, 29th Floor
Philadelphia, PA 19103

JAN 26 2011

Re: K110048
Trade/Device Name: CERSR® Electromyography System
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic Electromyograph
Regulatory Class: Class II
Product Code: IKN
Dated: January 6, 2011
Received: January 6, 2011

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

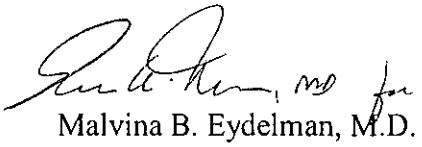
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110048

Indications for Use Statement

Device Name: CERSR® Electromyography System

Indications for Use:

The CERSR® Electromyography System is indicated for use to monitor and display the bioelectric signals produced by muscles to aid in the diagnosis and prognosis of muscular disease or dysfunction.

Prescription Use ___X__ (Per 21 C.F.R. 801.109) AND/OR Over-The-Counter Use____ (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

KRISTEN BOWSHER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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